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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,034

09/05/2003

James Hunter Boone

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

06/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,034	Applicant(s) BOONE ET AL.	
	Examiner JACOB CHEU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-11,13,14,17,18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-11,13,14,17,18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/2008; 1/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Applicant's amendment filed on 4/4/2008 and Rule 1.132 affidavit have been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2-6, 12, 15-16, 19-20 and 25 have been cancelled.
2. Claims 1, 7-11, 13-14, 17-18 and 21-24 are pending and under examination.
3. It is noted that the current case has been transferred to Examiner Jacob Cheu for examination.
4. The rejection over 35 USC 101 is withdrawn because in view of the specification and the affidavit. Accordingly, the rejection over 35 USC 112, first paragraph is withdrawn.
5. A new ground of rejection is set forth in this Office Action (see below).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7-9, 11, 13-14, 17-18 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Targan et al. (US 5750355).

With respect to claims 1, 8, 11 and 17, Targan et al. teach a method of determining ulcerative colitis (UC). Targan et al. teach obtaining a fecal sample from a person having inflammatory bowel disease, and using contacting the fecal sample with neutrophil

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cytoplasmic antigens (see example IV), and detecting the binding of neutrophil antigen bound with anti-neutrophil antibodies in the fecal sample, where the binding is indicative of the presence of the UC disease. Furthermore, it is noted that data from Table 1 indicate that the mean titers of anti-neutrophil antibody positive samples were significantly higher. Furthermore, Targan et al. also indicate that the measuring of anti-neutrophil antibodies from the fecal samples can also be used to differentiate the conditions of various diseases, including ulcerative colitis and Crohn's disease (see claim 15).

With respect to claim 7, the fecal samples are diluted in the ELISA (See Example Immunofluorescence Assay).

With respect to claim 9, Targan et al. teach using antibody, e.g. goat F(ab')₂ anti-human IgG(mu)-FITC to create a readable sample (See Example V; line 50-65).

With respect to claim 10, Targan et al. further teach using ELISA to detect complex, e.g. optical density.

With respect to claim 14, Targan et al. teach using ELISA. (see Example XI).

With respect to claim 13, the antibody used is an IgG (see Example V).

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With respect to claim 17-18, Targan et al. teach that measuring anti-neutrophil antibody can be used to detect UC and differentiating from Crohn's disease. *supra*.

With respect to claim 21, Targan et al. teach diluting fecal sample. *Surpa*.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Targan et al. as applied to claims 1 and 17 above, and further in view of Middeldorp et al. (US 20020169286).

Targan et al. reference has been discussed above, and Targan et al. teach using IgG antibody recognizing neutrophil- anti-neutrophil antibody complex in a sandwich assay (ELISA).

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However, Targan et al. do not explicitly teach using 450 nm spectrum for the detection under ELISA.

Middeldorp et al. teach using ELISA for analysis of analyte.

Middeldorp et al. teach using optical 450 nm for detection of IgG complex of human samples under ELISA (see section 0111)

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Targan et al. to use optical density of 450 nm detection, such as taught by Middeldorp, to detect the complex of IgG with neutrophil and anti-neutrophil antibodies. Using optical density under ELISA is well-known and widely practiced in the art and would requires merely routine skill in the field.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641